**Non-Confidential Summary of Safety and Effectiveness**
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1-Feb-08

Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015
Tel – 847-247-5609
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**Official Contact:** Ranndy Kellogg – VP Marketing & Product Development

**Proprietary or Trade Name:** 1500 Pro monitor

**Common/Usual Name:** Monitor, Physiological, Patient (without arrhythmia detection or alarms)

**Classification Name/Code:** DXN – System, Measurement, Blood-pressure, Non-invasive

**Device:** Model – 1500 Pro

**Predicate Devices:** Omron – HEM 780N3 – K061822

**Device Description:**
The Omron 1500Pro blood pressure monitor is a slightly modified version of the HEM-780N3 (K061822) blood pressure monitor.

The 1500Pro blood pressures monitor is intended to monitor:

- Blood pressure
- Pulse rate

The difference between the proposed 1500 Pro and the HEM-780N3 has to do with the cuff design. All other features, functions and technologies are identical to the predicate.

**Indications for Use:**

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 to 17 inches (22 – 42 cm) via an "arm in" cuff.

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

This blood pressure monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guidelines of 135/85 mm Hg.

The Omron 1500Pro model is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated. It is intended as an OTC device for home use.

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**Patient Population:** Adults

**Environment of Use:** Home settings

**Contraindications:** None

**Summary of substantial equivalence**

| **Model Name:** / **Specification** | **New device 1500 PRO** | **Predicate – K061822 HEM-780N3** |
|---|---|---|
| Measurement method | Cuff oscillometric method | Cuff oscillometric method |
| Measurement range | Pressure: 0 to 294 mmHg<br>Pulse Rate: 40 to 180 beats/min. | Pressure: 0 to 299 mmHg<br>Pulse Rate: 40 to 180 beats/min. |
| Pressure sensor | Electrostatic capacitive sensor | Electrostatic capacitive sensor |
| Applicable cuff | Arm-in / Mounted cuff | Wrap around cuff |
| Accuracy of pressure indicator | Within ±3 mmHg or 2 % of reading | Within ±3 mmHg or 2 % of reading |
| Accuracy of pulse rate | Within ±5 % of reading | Within ±5 % of reading |
| Cuff inflation | Automatic inflation with air pump | Automatic inflation with air pump |
| Pressure sensor | Semiconductor pressure sensor for wrapping cuff. | None |
| Slow cuff deflation (bleeding) | Deflation rate is controlled by an active electronic control valve by 4 to 11 mmHg/s depending on pulse rate. | Deflation rate is controlled by an active electronic control valve by 4 to 11 mmHg/s depending on pulse rate. |
| Rapid air release | By an active electronic control valve | By an active electronic control valve |
| Automatic shutting-down time | 5 minutes after a measurement completion | 5 minutes after a measurement completion |
| Irregular heart beat indication | displays an irregular heart beat symbol when 2 irregular heart beats were detected during a measurement. | displays an irregular heart beat symbol when 2 irregular heart beats were detected during a measurement. |
| Power source | AC adapter only | Battery (type "AA" × 4) or AC adapter |
| Display | Liquid crystal digital display | Liquid crystal digital display |
| Operating conditions | 10 to 40 °C (50 to 104 °F)<br>15 to 90 %RH | 10 to 40 □ (50 to 104 °F)<br>15 to 90 %RH |
| Storage conditions | -20 to 60 °C (-4 to 140 °F)<br>10 to 95 %RH | -20 to 60 □ (-4 to 140 °F)<br>10 to 95 %RH |
| Dimensions (mm) | 294 (W) × 286 (D) × 271 (H) mm | 131 (W) × 155 (D) × 85 (H) mm |
| Weight (not including batteries) | Approx. 2600g | Approx. 350 g |

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**Differences Between Other Legally Marketed Predicate Devices**

The Model 1500 Pro is viewed as substantially equivalent to the following predicate device – Omron HEM 780N3 – K061822.

The difference between the two devices is the style of cuff. 1500 pro has an "arm-in" style and the predicate a wrap around style cuff. All other features, specifications, etc. are otherwise identical.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2008

Omron Healthcare, Inc.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
3460 Pointe Creek Court # 102
Bonita Springs, FL 34134

Re: K080289
1500 Pro Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: February 01, 2008
Received: February 06, 2008

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080289

## Indications for Use Statement



**510(k) Number:** _____ (To be assigned)

**Device Name:** 1500 Pro

**Indications for Use:**

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 to 17 inches (22 – 42 cm) via an "arm in" cuff.

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It is intended as an OTC device for home use.

**Prescription Use** ___ **or** **Over-the-counter use** XX
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080289